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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,920	09/22/2006	Satoshi Tanabe	442P104	5892
42754 7590 02/17/2009 Nields, Lemack & Frame, LLC 176 E. Main Street Suite #5 Westborough, MA 01581				
EXAMINER				
BROWN, COURTNEY A				
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02/17/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/593,920

**Applicant(s)**

TANABE ET AL.

**Examiner**

COURTNEY BROWN

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)  
Paper No(s)/Mail Date 6/27/07, 11/22/06, and 6/25/08.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-7 are pending and are being examined for patentability.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. This application is a 371 of PCT/JP04/05770 filed on April 22, 2004.

### ***Information Disclosure Statement***

The Information Disclosure Statements (IDS) submitted on June 27, 2007, November 22, 2006, and June 25, 2008 have been considered by the examiner.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-5, and 7- 9 of copending Application No. 10/593,994 in view of James et al. (US Patent 6599941). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by co-pending application 10/593,994.

Copending claims 1,4-5, and 7- 9 and instant claims 1-7 both teach the use of 1-(2,6-dichloro-4- trifluoromethylphenyl)-3-(trifluoromethylthio)indole and 1-(2,6-dichloro-4-trifluoromethylphenyl)-3-(dichlorofluoromethylthio)indole for the control of parasites on companion animals. The difference between the invention of the instant application and that of copending application 10/593,994 is that the instant invention claims the use of the aforementioned compounds to control acarian parasites as opposed to fleas. James et al. teach that it is well known in the art that pesticides are often useful for controlling both insects and acarians such as mites and ticks (see column 8, lines 8-14). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in copending application 10/593,994.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Objections***

Claims 6 and 7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claims 6 and 7 depend from multiple dependent claim 5.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

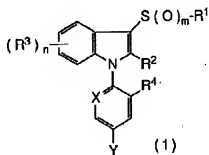
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotta et al. (JP 6092935) in view of Wichey-Lakshmanan (Advanced Drug Delivery Reviews).**

***Applicant's Invention***

Applicant claims an agent for controlling acarian parasites on mammals characterized by containing an N-substituted indole derivative represented by general formula (I):



wherein X is CH, N or C-halogen atom; Y is a hydrogen atom, a Cl-C5 alkyl group optionally substituted by a halogen atom(s), a C2-C5 alkenyl group optionally substituted by a halogen atom(s), a C2-C5 alkynyl group optionally substituted by a halogen atom(s), a Cl-C5 alkoxy group optionally substituted by a halogen atom(s), a halogen atom, a cyano group or a nitro group; R<sup>1</sup> is a Cl-C5 alkyl group optionally

substituted by a halogen atom(s), or a C1-C5 alkoxy group optionally substituted by a halogen atom(s); R2, R3 and R4 are independently a hydrogen atom, a C1-C5 alkyl group optionally substituted by a halogen atom(s), a C2-C5 alkenyl group optionally substituted by a halogen atom(s), a C2-C5 alkynyl group optionally substituted by a halogen atom(s), a halogen atom, a cyano group, a carboxyl group, a C1-C5 alkoxycarbonyl group optionally substituted by a halogen atom(s), a C1-U5 acyl group optionally substituted by a halogen atom(s), a nitro group, a cyano group, a thiocyanato group, a C1-C5 alkoxy group optionally substituted by a halogen atom(s), or S(O)<sub>k</sub>R5 wherein k is 0, 1 or 2 and R5 is a C1-C5 alkyl group optionally substituted by a halogen atom(s); m is 0, 1 or 2; and n is 1, 2, 3 or 4.

***Determination of the scope and the content of the prior art  
(MPEP 2141.01)***

Hotta et al. teach a composition comprising N-substituted indole derivatives of instant Formula 1 and their use as an insecticide in order to protect man or animal from parasitic hindrance ([0001], claim 1 and 5 of instant application). Hotta teaches the instant N-substituted indoles of formula (I) and their use in an insecticidal composition wherein X is N; Y is a C1-C5 alkyl optionally substituted with a halogen atom; R1 is a C1-C5 alkyl group; and R2, R3, and R4 are independently a hydrogen atom or a C1-C5 alkyl group (see claim 1, General Formula 1 of Hotta et al., claims 1-4 of instant application). Hotta teaches that the indole derivatives can be mixed with a liquid carrier, an emulsifier, a dispersant, or a disintegrator among other excipients (paragraphs [0017]-[0019]).

***Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)***

The difference between the invention of the instant application and that of Hotta et al. is that the instant invention claims a shampoo or rinse and liquid drops comprising the N-substituted indole derivatives of instant Formula 1 as opposed to being silent. For this reason, the teaching of Witchey-Lakshmanan is joined. Witchey-Lakshmanan teach, in a comparison of the advantages and disadvantages of various types of topical products for the control of fleas and ticks, that with the use of shampoos on animals, the active agent has a chance to permeate entirely through the fur onto the skin of said animal (see page 114, Table 1). Witchey-Lakshmanan also teaches that commercially available topical liquids (i.e. spot-ons) are very easy to use and have a duration as long as 1 month.

***Finding of prima facie obviousness***

***Rationale and Motivation (MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at an agent for controlling acarian parasites on mammals comprising an N-substituted indole derivative represented by general formula (I). Witchey-Lakshmanan teaches that there are advantages through the use of shampoos and liquid drops for the control of parasites on animals. One would have been motivated to make this combination in order to receive the expected benefit of having an agent for controlling acarian parasites on mammals



that, when used as a shampoo, provides opportunity for maximum efficacy and when used as liquid drops, provides a low level of transference onto the mammal's surrounding environment (see page 114 of Witchey-Lakshmanan). Thus, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art.

Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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